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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,302	10/31/2003	William Bedingham	56160US015	1395

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,302	Applicant(s) BEDINGHAM ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 19-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>110304, 102104, 112403, 103103</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1) Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-12, drawn to a culture device, classified in class 435, subclass 288.3.
- II. Claims 13-18, drawn to a system for harvesting cells, classified in class 435, subclass 286.2.
- III. Claims 19-26, drawn to a method for harvesting cells, classified in class 435, subclass 39.
- IV. Claims 27-31, drawn to a computer readable medium, classified in class 382, subclass 133.

Inventions of Group II and Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system for harvesting cells can be used in conjunction with any type of culture device. The subcombination has separate utility since cells can be grown and analyzed using the culture device without the implementation of a harvesting procedure.

Inventions of Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case it is possible to use the disclosed method for harvesting cells with any type of thin film culture device in addition to the one of Invention I. Furthermore, the cell colonies of the culture device could be picked using a different automated method, or simply manually.

Inventions of Group I and Group IV are directed to related apparatuses. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the disclosed culture device and the disclosed computer readable medium are related only in that the computer readable medium is used to analyze the contents of the culture device. Otherwise, the inventions have materially different designs, modes of operation, and functions.

Inventions of Group III and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the

Art Unit: 1744

process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus does not require the use of a thin film culture device, whereas the method can only be accomplished using a thin film culture device. The apparatus could be used to harvest cells from culture devices that are different from those disclosed in the method.

Inventions of Group II and Group IV are directed to related apparatuses. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the disclosed harvesting system and the disclosed computer readable medium are related only in that the computer readable medium is used to provide instructions on how to operate the harvesting system. Otherwise, the inventions have materially different designs, modes of operation, and functions.

Inventions of Group III and Group IV are directed to related processes and products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use

Art Unit: 1744

together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the disclosed harvesting process and the disclosed computer readable medium do not share any common structural features, functions, or effects.

During a telephone conversation with Daniel Pastirik on 5 June 2006 a provisional election was made with traverse to prosecute the invention of Group II, claims 13-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12 and 19-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2) Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by

Parekh (US 6064754).

Parekh discloses a system that comprises a scanner, a processing unit and a picking apparatus. Column 3, line 60 to column 4, line 39 indicates that the system is arranged to selectively remove a specific biomolecule from a plate. Even though Parekh offers many examples in which the biomolecule is a protein or a nucleic acid, the device can be used to harvest biological samples that "comprise cells or medium conditioned by any cell, tissue, or organ." The disclosed device is inherently able to pick and harvest selected cells growing on a culture device since a scanner, processing unit, a picking apparatus are all provided. Column 18, line 21 to column 19, line 43 teaches the use of a scanner that is able to image the cells using luminescence detected following fluorescent staining. Column 13, line 14 to column 14, line 7 discloses that a processing unit is used to direct the movement of a picking apparatus based on information obtained by the scanner. This arrangement is illustrated in Figure 3. The scanner provides an image file to the processing unit, and the picking apparatus harvests the desired cells based on analysis of the image file.

3) Claims 13, 14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Stubbings (WO 9212233).

With respect to claims 13 and 17, Stubbings discloses a system for harvesting cells from a colony on an agar culture device. The system comprises a scanner (Figure 1:24), a processing unit, and a picking apparatus (Figure 1:22). This is disclosed on page 6. Stubbings indicates on pages 9, 10 and 13 that the locations of colonies are identified by the scanner, and that a computer is used to

Art Unit: 1744

regulate the movement of the picking apparatus according to the information obtained by the scanner. The scanner provides an image file to the computer, and the picking apparatus automatically harvests the desired cells based on analysis of the image file. On page 9, Stubbings additionally indicates that the system includes an orienting unit that works to position the culture device. A pivoted bar (Figure 5:80) and a stop (Figure 5:82) ensure that the culture device is correctly inserted during harvesting.

With respect to claims 14 and 18, Stubbings discloses the apparatuses in claims 13 and 14, wherein the orienting unit has receiving structures adapted to receive corresponding positioning structures in the culture device. As previously described, the orienting unit of the picking apparatus is comprised of a pivoted bar and a stop. The pivoted bar and stop are adapted to interact with the walls of the culture device. In this way, the exterior walls of the culture device act as positioning structures that cooperate with the picking apparatus orienting unit.

4) Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Uber "Application of robotics and image processing to automated colony picking and arraying."

Uber discloses in the *Introduction* an apparatus for picking cell colonies comprising an apparatus bed for arranging a sample container comprising a plurality of cell colonies. The *Imaging System* and *Imaging Procedure* sections disclose a camera and image processing software useful in identifying animal cell colony locations from captured images. A picking head is movable around the

Art Unit: 1744

apparatus bed using positioning motors to cell colony locations identified by the image processing software. The tip of the picking head is equipped with pipettes and syringes capable of dispensing fluids. See the *Robotic System* section. The distal end of the pipette is introduced by a drive into a sample container offset from a cell colony.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

Art Unit: 1744

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5) Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubbings (WO 9212233) as applied to claims 13 and 17, and further in view of Barbera-Guillem (US 6455310).

Stubbings discloses the apparatus set forth in claims 13 and 17 as set forth in the 35 U.S.C. 102 rejections above. However, if the walls of the culture devices cannot be considered positioning structures that receive corresponding structures located at the orienting unit, then Stubbings fails to anticipate claims 14 and 18.

Barbera-Guillem discloses a cell culturing device that can be accommodated and held in position by a standard mechanical stage holder for a microscope. This is disclosed in column 6, lines 14-52 and column 11, lines 27-67. Barbera-Guillem discloses in column 12, lines 21-67 that the cell culturing device and its corresponding holder are held together using a mechanical means such as a snap-fitting, pressure fitting, or locking device. It is known in the art that these types of devices involve interacting structural components on both of the pieces that are being joined.

Stubbings and Barbera-Guillem are analogous art because they are from the same field of endeavor regarding systems for analyzing cell culture devices.

Art Unit: 1744

At the time of the invention, it would have been obvious to modify the cell culture device disclosed by Stubbings in order to add additional structural features that interact with structural features present on the orienting unit. This interaction would produce a mechanical interaction, such as a snap-fitting mechanism, that would ensure that the cell culture device is securely positioned on the orienting unit. This would have been beneficial because it would have guaranteed that the cell culture device would not slide out of place once it has been correctly positioned.

6) Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stubbings (WO 9212233) and Barbera-Guillem (US 6455310) as applied to claim 14, and further in view of Bevirt (US 20020150450).

Stubbings and Barbera-Guillem disclose the apparatuses set forth in claim 14 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the orienting unit further comprises a compliant pad.

Bevirt discloses a robotic arm for automatically moving biological containers such as microtiter plates and cell culture devices. In paragraph [0029], Bevirt discloses that the robotic arm (Figure 1:2) is attached to a plate holder. The plate holder includes rubber pads that contact the biological container during transportation. Rubber pads are known in the art to be compliant materials.

Art Unit: 1744

Stubbings, Barbera-Guillem and Bevirt are analogous art because they are from the same field of endeavor regarding apparatuses for the automatic handling and transportation of biological containers.

At the time of the invention, it would have been obvious to provide the orienting unit disclosed by Stubbings and Barbera-Guillem with a rubber, compliant pad. Bevirt teaches that rubber pads are beneficial when added to container handling units because they facilitate surface contact between the handling unit and the container. In light of this teaching, it would have been obvious to utilize rubber pads in Stubbings device in order to ensure that there is adequate frictional contact between the cell culture container and the orienting unit when the cell culture container is correctly aligned in position for harvesting procedures. Rubber pads would ensure that the cell culture container does not slide out of position once it has been properly oriented.

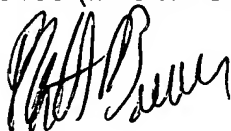
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NAB



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